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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,764	10/24/2003	Stuart B. Levy	PAZ-205CP	8952

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EXAMINER	
MAKAR, KIMBERLY A	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/692,764	LEVY ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7, 36-47 and 54, drawn to a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a plant or virus, classified in class 424, subclass 93.1.

II. Claims 8, 36-47 and 54, drawn to a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a human, classified in class 424, subclass 1.11.

III. Claims 12-35, drawn to methods of modulating RNA, classified in class 435, subclass 91.3.

IV. Claims 48-54, drawn to a method for identifying tetracycline compounds for disorders treated by modulation of RNA, classified in class 435, subclass 6.

V. Claims 55-56, drawn to a packaged composition comprising instructions for using a tetracycline compound, the tetracycline compound, and a pharmaceutically acceptable carrier, classified in class 514, subclass 152.

2. Claims 1-6, 10 and 11 link(s) inventions I and II. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s),

claim 1-6, 10 and 11. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention I, a methodology of treating a subject for

a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a plant or virus will have different reagents, concentrations, protocols, conditions, etc. than the methodology of invention II, a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a human. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search of the method of group I would not be co-extensive with the methods of group II, and hence would be burdensome.

4. Inventions I and III are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention I, a methodology of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a plant or virus will have different reagents, concentrations, protocols, conditions, etc. than the methodology of invention III of modulating RNA. The methodology of invention III does not require the tetracycline compound of invention I, nor the subject of invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter

and there is nothing of record to show them to be obvious variants. A search of the method of group I would not be co-extensive with the methods of group III, and hence would be burdensome.

5. Inventions I and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention I, a methodology of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a plant or virus will have different reagents, concentrations, protocols, conditions, etc. than the methodology of invention IV drawn to a method for identifying tetracycline compounds for disorders treated by modulation of RNA. The methodology of invention IV does not require the tetracycline compound of invention I, nor the subject of invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search of the method of group I would not be co-extensive with the methods of group IV, and hence would be burdensome.

6. Inventions I and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention I, a methodology of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a plant or virus is distinct from the a packaged composition comprising instructions for using a tetracycline compound, the tetracycline compound, and a pharmaceutically acceptable carrier of invention V. The methodology of invention I can be performed without the composition of invention V, and the composition of invention V can be used without the methodology, and comprises additional reagents than those of invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search for the compositions of invention V would not be co-extensive with a search of the methodology of invention I, and hence would be burdensome.

7. Inventions II and III are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention II, a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a human

is distinct from the methodology of invention III. Invention II, will have different reagents, concentrations, protocols, conditions, etc. than the methodology of invention III drawn to a method of modulating RNA. The methodology of invention III does not require the tetracycline compound of invention II, nor the subject of invention II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search of the method of group II would not be co-extensive with the methods of group III, and hence would be burdensome.

8. Inventions II and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention II, a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a human is distinct from the methodology of invention IV, drawn to a method for identifying tetracycline compounds for disorders treated by modulation of RNA. The methodology of invention IV does not require the tetracycline compound of invention II, nor the subject of invention II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious

variants. A search of the method of group II would not be co-extensive with the methods of group IV, and hence would be burdensome.

9. Inventions II and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention II, a method of treating a subject for a disorder treated by modulation of RNA comprising administering to said subject an effective amount of a substituted tetracycline compound wherein the subject is a human is distinct from the a packaged composition comprising instructions for using a tetracycline compound, the tetracycline compound, and a pharmaceutically acceptable carrier of invention V. The methodology of invention II can be performed without the composition of invention V, and the composition of invention V can be used without the methodology, and comprises additional reagents than those of invention II. . Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search for the compositions of invention V would not be co-extensive with a search of the methodology of invention II and thus would be burdensome.

10. Inventions III and IV are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the

inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed differ in scope. Invention III a method of modulating RNA is distinct from the methodology of invention IV, drawn to a method for identifying tetracycline compounds for disorders treated by modulation of RNA. The methodology of invention IV does not require the same protocols, reagents or tetracycline compounds required in invention III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. A search of the method of group III would not be co-extensive with the methods of group IV, and hence would be burdensome.

11. Inventions III and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention III, a method of modulating RNA is distinct from the packaged composition comprising instructions for using a tetracycline compound, the tetracycline compound, and a pharmaceutically acceptable carrier of invention V. The methodology of invention III can be performed without the composition of invention V, and the composition of invention V can be used without the methodology, and comprises additional reagents than those of invention III. Furthermore, the inventions as claimed do not encompass overlapping subject matter

and there is nothing of record to show them to be obvious variants. A search for the compositions of invention V would not be co-extensive with a search of the methodology of invention III, and thus would be burdensome.

12. Inventions IV and V are directed to related inventions. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct. Invention IV, drawn to a method for identifying tetracycline compounds for disorders treated by modulation of RNA is distinct from the a packaged composition comprising instructions for using a tetracycline compound, the tetracycline compound, and a pharmaceutically acceptable carrier of invention V. The methodology of invention IV can be performed without the composition of invention V, and the composition of invention V can be used without the methodology, and comprises additional reagents than those of invention IV. A search for the compositions of invention V would not be co-extensive with a search of the methodology of invention IV and would thus be burdensome. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

13. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

14. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

15. This application contains claims directed to the following patentably distinct species: method of using a tetracycline compounds (for example, one of table 2). The species are independent or distinct because the compounds of table 2 are different structures with different functions, and as claimed they can promote RNA splicing or inhibit RNA splicing, promote initiation of translation or inhibit initiation of translation.

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, from within the elected Group I or II if elected for search purposes, even though this requirement is traversed. Applicant must provide the chemical structure of the elected formula. Currently, claims 1, 11 and 12 are generic.

17. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

18. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

19. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

20. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

21. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/01/04/07

DAVID GUZO
PRIMARY EXAMINER